

U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

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| B/O Form PTO-1390 | | Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing Under 35 USC 371 | | Attorney's Docket Number HIRA3010/REF U.S. Application Number (if known) 10/591186 | |
| International Application Number PCT/JP2004/012848 | | International Filing Date September 3, 2004 | | Priority Date Claimed March 3, 2004 | |
| Title of Invention PHARMACEUTICAL COMPOSITION FOR LOWERING BLOOD SUGAR LEVEL | | | | | |
| Applicant(s) for DO/EO/US Akira HIRASAWA and Gozo TSUJIMOTO | | | | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items under 35 USC 371: | | | | | |
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 USC 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 USC 371. 3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 USC 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 USC 371(b) and PCT Articles 22 and 39(1). 4. <input checked="" type="checkbox"/> The U.S. has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed 35 USC 371(c)(2). <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input checked="" type="checkbox"/> A translation of the International Application into English (35 USC 371(c)(2)). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 USC 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 USC 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 USC 371(c)(4)). (<input type="checkbox"/> Executed <input type="checkbox"/> Unexecuted) 10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 USC 371(c)(5)). <p><i>Items 11 to 16 below concern other document(s) or information included:</i></p> <ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A preliminary amendment. 14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and U.S.C. 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English translation of the international application under 35 U.S.C. 154(d)(4) 20. <input checked="" type="checkbox"/> Other items or information: International Search Report, Abstract | | | | | |

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|---|--------------|--|---------------|--|---------|
| Application Number (if Known) 10/591186 | | International Application Number PCT/JP2004/012848 | | Attorney's Docket Number HIRA3010/REF | |
| | | | | Calculations | PTO USE |
| 21. The following fees are submitted: | | | | | |
| <input checked="" type="checkbox"/> a) Basic national fee.....\$300.00 <input checked="" type="checkbox"/> b) Examination fee\$200.00 | | | | \$500.00 | |
| <input checked="" type="checkbox"/> c) Search Fee: <input type="checkbox"/> If the written opinion of the ISA/US or the International preliminary examination report prepared b IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0.00 <input type="checkbox"/> Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100.00 <input checked="" type="checkbox"/> International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....\$400.00 <input type="checkbox"/> All other situations.....\$500.00 | | | | \$400.00 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fractions thereof. | | | | | |
| Total Sheets | Extra sheets | Number of each additional 50 or fractions thereof (round up to a whole number) | RATE | | |
| - 100 = | /50= | | x \$250.00 | | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)). | | | | | |
| CLAIMS | NUMBER | NUMBER EXTRA | RATE | | |
| Total Claims | 17 -20 = | | x \$50.00 | | |
| Independent Claims | 3 -3 = | | x \$200.00 | | |
| Multiple Dependent Claims (if applicable) | | | + \$360.00 | | |
| TOTAL OF ABOVE CALCULATIONS | | | | \$ 900.00 | |
| <input checked="" type="checkbox"/> Reduction by ½ for filing by small entity, if applicable. Small Entity Status is asserted pursuant to 37 CFR 1.27 for this application. | | | | \$ 450.00 | |
| SUBTOTAL | | | | \$ 450.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). | | | | | |
| TOTAL NATIONAL FEE | | | | \$ 450.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property. | | | | | |
| TOTAL FEES ENCLOSED | | | | \$ 450.00 | |
| | | | Amount to be: | Refunded: | |
| | | | | Charged: | |

- a. ☒ A check in the amount of \$ 450.00 to cover the fees is enclosed.
 b. ☐ Please charge my **Deposit Account Number 02-0200** in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.
 c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to **Deposit Account Number 02-0200**. A duplicate copy of this sheet is enclosed.

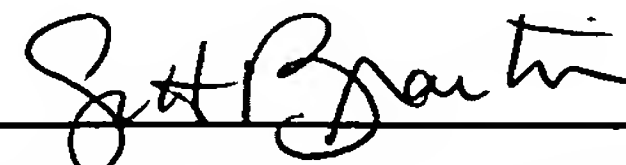
Note: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

23364

Customer Number
Phone: (703) 683-0500

DATE: August 30, 2006

Respectfully submitted,



Attorney for Applicant Scott A. Brairton
Registration Number: 55,020